

Appln. No. 09/367,714  
Amd. dated January 12, 2004  
Reply to Office Action of September 12, 2003

**REMARKS**

The Office Action mailed on September 12, 2003 and the cited and applied references have been carefully reviewed. Claims 1-14, 20, 21, 27-35 and 37 have been examined in this case. No claim is allowed, although claims 2-6, 12-14, 20, 21, 35, and 37 are only objected to as being dependent from rejected claims.

Claims 1-6, 8-14, 20, 21, 27-29, 35 and 37-39 presently appear in this application and define patentable subject matter warranting their allowance. Claims 7 and 30-34 have been cancelled. New claims 38 and 39 have been added. Reconsideration and allowance are hereby respectfully solicited.

The claims 2, 12, 14 and 20 that are only objected to as being dependent from rejected claims are now rewritten in independent form, thereby placing claims 2-6, 12-14, 20 and 21 in condition for allowance. New claim 39 has been added as an independent claim thereby placing claims 35 and 37 in condition for allowance.

Claims 1, 7-11, and 27-33 have been rejected under 35 U.S.C. §103 as being unpatentable over Shai, *J. Biol. Chem.* 271:7305 (1996) on the ground that Shai teaches that the

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peptide designated (D)P<sup>7</sup>L<sup>18</sup>L<sup>19</sup> is antibacterial but non-hemolytic. The examiner states that "Shai does not disclose that if one of the amino acid side chains is extended by one methylene unit, that cytolytic activity will be retained, as directed to claims 1 and 7-11. However, a peptide biochemist of ordinary skill would have expected, a priori, that when a side chain of one amino acid in a peptide is extended by one methylene unit, the biological activity would remain substantially the same [*In re Shetty* (195 USPQ 753) and *In re Hass and Susie* (60 USPQ 544)]." It is further mentioned in the Office Action that "Yechiel Shai is of the opinion that adding or deleting a single methylene unit from the side chain of an amino acid that is present in a peptide **may** abolish or reduce the biological activity of the peptide. However, no evidence of this effect has been made of record. In the event that such evidence is made of record, the relevance of this evidence to the claimed invention would then be assessed." This rejection is respectfully traversed.

With due respect to the examiner, the examiner appears to have misunderstood the present invention as defined in claims 1(B) and 7-11. Claim 1(B) has now been amended to make clear that the definition does not encompass mere

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modifications in the amino acid residues of natural peptides. The peptide (D)P<sup>7</sup>L<sup>18</sup>L<sup>19</sup> disclosed by Shai is a derivative of the natural peptide pardaxin (it is the peptide **16** disclosed as being hemolytic on page 26 of the present specification) in which the L-amino acids P<sup>7</sup>L<sup>18</sup>L<sup>19</sup> have been replaced by the D-isomers. Thus, this is a case in which the peptide in the L-configuration would be found in nature, contrary to the definition of claim 1(B). Accordingly, there is no need to provide evidence that adding or deleting a single methylene unit from the side chain of an amino acid in such a peptide would affect the biological activity of the peptide because this is not what is encompassed in claims 1(B) and 7-11 (present claims 8-11). The disclosures and teachings of the applied Shai reference simply cannot lead one of ordinary skill in the art to the present invention.

Reconsideration and withdrawal of the rejection are therefore respectfully requested.

Claim 34 has been rejected under 35 U.S.C. §103 as being unpatentable over Shai or Maloy (U.S. Patent 5,792,831). Claim 34 is now cancelled, thereby mooted the rejections over Shai or Maloy insofar as claim 34 is concerned.

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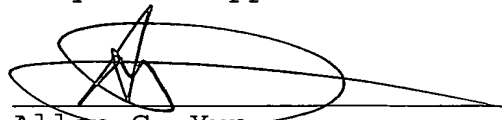
New claim 38, which is drawn to a composition and is dependent from claim 1, is added and is patentable for the same reason that claim 1 is patentable over the prior art. Applicants would like to draw the examiner's attention to similar claims granted by the USPTO in recent patents issued to the assignee and to others such as US 6,172,038, US 6,180,103, US 6,239,107, US 6,664,369 and US 6,504,005. Reconsideration and allowance of claims 27-29 are hereby respectfully solicited.

In view of the above, the claims comply with 35 U.S.C. §112 and define patentable subject matter warranting their allowance. Favorable consideration and early allowance are earnestly urged.

Respectfully submitted,

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